Docket No. 9222.16565-CIP DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Utley et al. Serial No.: Unknown Filed: Unknown

For:

Systems and Methods for Treating Dysfunctions in the Intestines and Rectum

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION (37 CFR 1.97(b))

NOTE: "An information disclosure statement shall be considered by the Office if filed: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in S 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 CFR 1.97(b).

NOTE: The "filing date of a national application" under 37 CFR 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 CFR 1.53(b) as "the date on which: (1) A specification containing a description pursuant to S 1.71 and at least one claim pursuant to S 1.75; and (2) any drawing required by S 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by S 1.41." 37 CFR 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. S 371(c) within the periods set forth in S 1.494 or S 1.495. 35 U.S.C. S 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 CFR 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed WITHIN THREE MONTHS OF THE FILING DATE OF THE APPLICATION OR DATE OF ENTRY INTO THE NATIONAL STAGE OF AN INTERNATIONAL APPLICATION OR BEFORE THE MAILING DATE OF A FIRST OFFICE ACTION ON THE MERITS, WHICHEVER EVENT OCCURS LAST. 37 CFR 1.97(b).

NOTE "NO CERTIFICATION OR FEE IS DUE WHEN THE FILING IS MADE WITHIN THE ABOVE TIME PERIOD. IT IS ADVISABLE TO ENSURE THAT NO OFFICE ACTION HAS BEEN MAILED IF THE DISCLOSURE STATEMENT IS DELAYED UNTIL AFTER THREE MONTHS FROM FILING.

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 CFR 1.8, or Express Mail certificate under 37 CFR 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATE OF MAILING (37 CFR 1.8(a)) or (37 CFR 1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United State Postal Service on the date shown below as Express Mail Label No. <u>EV 317559707</u> in an envelope addressed as follows: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

Linda S. Wenzel

Type or print name of person mailing paper

(Signature of person mailing paper)

Date: 29 September 2003

NOTE:

"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE:

"An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 CFR 1.142) or just a requirement for additional fees to have a claim considered (37 CFR 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING:

"A PETITION FOR SUSPENSION OF ACTION TO ALLOW APPLICANT TIME TO SUBMIT AN INFORMATION DISCLOSURE STATEMENT WILL BE DENIED AS FAILING TO PRESENT GOOD AND SUFFICIENT REASONS, SINCE 37 CFR 1.97 PROVIDES ADEQUATE RECOURSE FOR THE TIMELY SUBMISSION OF PRIOR ART FOR CONSIDERATION BY THE EXAMINER." NOTICE OF JULY 6, 1992 (1141 O.G. 63).

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima face* prior art reference against the claims of the present application.

COPIES OF THE DOCUMENTS LISTED ON THE ATTACHED FORM PTO-1449 CAN BE FOUND IN THE FILE WRAPPER OF PARENT APPLICATION SERIAL NO. 09/556,169 FILED 21 April 2000 AND ARE THEREFORE NOT INCLUDED WITH THIS SUBMISSION.

Should any fees be necessary in connection with this submission, please charge same to Account No. 06-2360.

Date 29 September 2003

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Signature of Attorney of Record

Patricia A. Limbach

Type or Print Name of Attorney of Record

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) APPLICANT Utley et al. Customer No. 26308 FILING DATE Unknown GROUP Unknown

U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subcless	Filing Date (If Appropriate)
	5,370,675	12/94	Edwards et al.			
	5,873,877	2/99	McGaffigan et al.			
	6,017,338	1/00	Brucker et al.			
	6,231,571	5/01	Ellman et al.			
	5,451,223	9/95	Ben-Simhon			
	5,709,224	1/98	Behl et al.			
	6,009,877	1/00	Edwards			
	5,403,311	9/95	Abele et al.			
	5,827,276	10/98	LeVeen et al.		V	
	6,092,528	7/00	Edwards			
	6,056,744	5/00	Edwards			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	Class	Subclass	Translation Yes No
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

			
EXAMINER	DATE CON	NSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this of with next communication to applicant.

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	5,370,675 12/94			Edwards et al.					- Appropriate	
	6,325,798	12/01		ds et al.		7				
	6,419,673	7/02		Edwards et al.						
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